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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,112	03/05/2007	Craig A. Judy	0765-005US1	1150

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LESLIE MEYER-LEON, ESQ.
IP LEGAL STRATEGIES GROUP P.C.
1480 FALMOUTH ROAD
P.O. BOX 1210
CENTERVILLE, MA 02632-1210

EXAMINER	
PURDY, KYLE A	
ART UNIT	**PAPER NUMBER**
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,112	JUDY ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/08/2008 and 06/26/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *15-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2 pages (07/22/2008 and 06/26/2008).

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 06/26/2008 wherein claims 2-14 have been amended.

2. Claims 1-14 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 06/26/2008 regarding the objection of claims 7-9 made by the have been fully considered and they are persuasive. This objection has been mitigated by amendment.

4. Applicants arguments filed 06/26/2008 regarding the rejection of claims 1-5 and 10 made by the Examiner under 35 USC 102(b) over Dandiker et al. (US 5425950) have been fully considered but they are not persuasive.

5. Applicants arguments filed 06/26/2008 regarding the rejection of claim 1-5 and 10 made by the examiner under 35 USC 102(b) is **MAINTAINED** for the reasons of record in the office action mailed on 03/26/2008.

6. In regards to the 102(b) rejection, Applicant asserts the following:

A) Dandiker does not properly anticipate the instantly rejected claims because Dandiker disclosure, Example 10 for instance, does not disclose a tablet with a core surrounded by a rapid-release mantle free of sumatriptan.

7. With respect to assertion A, the Examiner respectfully disagrees. Albeit true that Example 10 disclosed by Dandiker has three discrete layers of the following:

I) a core containing sumatriptan;

II) an immediate release coating free of sumatriptan; and

III) a sustained release coating containing sumatriptan.

Although, Dandikers tablet has an outermost layer containing sumatriptan, Dandiker nonetheless anticipates the instantly rejected claims. Dandiker discloses the limitations required by the claims in that they teach a core containing sumatriptan and a rapid release mantle free of sumatriptan that entirely surrounds the core. To be certain that applicants coating is not on the outer surface of the tablet, the definition of the 'mantle' is applied. 'Mantle,' as defined by Dictionary.com, is something that covers or envelops and in geological terms is the portion of the earth that lies between the crust and the core. Thus, Applicants use of the term 'mantle' in no way limits that structure to be the outermost surface, rather mantle indicates that it is probably an intermediate layer between a core structure and outermost surface. It is noted that Applicant frequently refers to the term 'outer' in their response to this rejection but it is unclear why. Applicant does not limit the mantle to be the 'outer' layer. In fact, the Examiner has searched Applicants specification for the term 'outer', 'outer' is not mentioned anywhere. Finally, it should be pointed out that Applicant uses the term 'comprising' which allows for unspecified modifications to be encompassed in the art and still anticipate the claims, i.e. the outermost core disclosed by Dandiker.

8. Applicants arguments filed 06/26/2008 regarding the rejection of claims 1-5 and 10-14 made by the Examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view of Lerner et al. (US2004/0052843) have been fully considered but they are not persuasive.

9. Applicants arguments filed 06/26/2008 regarding the rejection of claim 1-5 and 10-14 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 03/26/2008.

10. In regards to the 103(a) rejection, Applicant asserts the following:

A') Dandiker does not teach Applicants broadest claim, so Dandiker can not properly be used to obviate the claims. Dandiker does not properly meet the limitations of the instantly rejected claims because Dandikers disclosure, Example 10 for instance, does not disclose a tablet with a core surrounded by a rapid-release mantle free of sumatriptan; and

B') The tablets disclosed by Lerner do not disclose the tablet as being completely coated by the coating layer.

11. With respect to assertion A', the Examiner directs Applicant to the response to assertion A) above.

12. With respect to assertion B', it is acknowledged that Lerner teaches a tablet wherein the coating layer does not entirely coat the drug containing core. However, this point is moot because the primary teaching to Dandiker teaches coating the drug containing core entirely. Lerner is relied because it teaches a sumatriptan composition comprising a core wherein 80% of the core is dissolved within 30 minutes and the coating of the core is entirely dissolved within an hour. Lerner is relied upon to show Applicants properties are obvious and are commonly subjected to optimization. As indicated in office action mailed on 03/26/2008, the rate of disintegration of core and coating structures are routinely subjected to optimization. It is well known in the art that if one desired to adjust the rate of release for a tablets core and/or coating, adjusting the amount of disintegrant, for one, would result in altering the rate of disintegration.

Finally, one would be motivated to modify Dandikers sumatriptan core such that it was immediate release because it would be favorable to deliver the drug immediately to relive the subjects migraine rather than a slow release composition which would require the subject to wait for relief.

13. Applicants arguments filed 06/26/2008 regarding the rejection of claims 1 and 5-9 made by the Examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view Lieberman et al. (Pharma. Dosage Forms, 1990) have been fully considered but they are not found persuasive.

14. Applicants arguments filed 06/26/2008 regarding the rejection of claims 1 and 5-9 made by the examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view Lieberman et al. (Pharma. Dosage Forms, 1990) is **MAINTAINED** for the reasons of record in the office action mailed on 03/26/2008.

15. In regards to the 103(a) rejection, Applicant asserts the following:

A'') Dandiker does not teach Applicants broadest claim, so Dandiker can not properly be used to obviate the claims. Dandiker does not properly meet the limitations of the instantly rejected claims because Dandikers disclosure, Example 10 for instance, does not disclose a tablet with a core surrounded by a rapid-release mantle free of sumatriptan;

16. With respect to assertion A'', the Examiner directs Applicant to the response to assertion A) above.

Maintained Rejections

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. **Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dandiker et al. (US 5425950; of record).**

Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. The composition of the reference comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active H_2-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for an immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). It is clear from Example 10 that, aside from sumariptan, the core and the coating contain substantially the same ingredients (see instant claim 10). It is also clear that upon coating of the core with the polymer layer, the core is entirely surrounded because the diameter and thickness both are substantially increased. The tablet formulation of Example 10 contains 50 mg of sumatriptan (see column 14, lines 30-35; see instant claim 4) and the weight ratio of mantle to core is 1.3:1 as the core had a weight of 100 mg and the coating had a weight of 130 mg (230 mg – 100 = 130 mg; see column 14, lines 45-50; see instant claims 2-3). This corresponds to a weight ratio of mantle to core of 1.3:1.

19. Thus, the limitations of the instant claims are met entirely by the reference of Dandiker.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. **Claims 1-5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US 5425950; of record) in view of Lerner et al. (US 2004/0052843).**

22. Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. specifically the invention comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active H_2-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for a immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). The core apart from the suamtriptan in the core contains substantially the same ingredients asa the mantle (see instant claim 10). Moreover, in the tablet formulation the core contains 50 mg of sumatriptan (see column 14, lines 30-35; see instant claim 4). The resulting core had a weight of

100 mg and the coating applied to a core had a weight of 130 mg (230 mg – 100 = 130 mg; see column 14, lines 45-50). This corresponds to a weight ratio of mantle to core of 1.3:1 (see instant claims 2-3).

23. Dandiker fails to teach the tablet wherein both the core and the mantle dissolve rapidly in the stomach wherein at least 90% of the tablet is dissolved after 10 minutes. Dandiker also fails to teach that the core and the mantle disintegrate over substantially the same time period wherein the mantle is at least 95% dissolved and the core is at least 90% dissolved after 10 minutes.

24. Lerner et al. ('Lerner) is drawn to a controlled release dosage form having a zero order release profile. It is taught that drug delivery is to be tailored to the needs of therapy and that the delivery profile can be one of immediate release in the stomach (see [0003]; see instant claim 11). Example 5 of Lerner is drawn to a tablet possessing an inner core and an outer mantle. The inner core contains sumatriptan succinate, microcrystalline cellulose, lactose, croscarmellose sodium and magnesium stearate. The core is then coated with a mixture of sucrose, microcrystalline cellulose, menthol and magnesium stearate. The tablet was then tested for its drug release profile and it was found that 80% of the sumatriptan in the core was released in 30 minutes (see [0142]; see instant claims 13-14).

25. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of Dandiker and Lerner with a reasonable expectation for success in arriving at a tablet comprising a core comprising sumatriptan and mantle free of sumatriptan wherein the weight ratio of the mantle to the core is less than 1.5:1. The significance of Dandiker is that it teaches the basic requirements for the excipients contained in the core and the mantle of the dosage form (see discussion above). However, Dandiker does

not disclose any information regarding the rate of release such that sumatriptan is 90% released within 10 minutes. However, Lerner describes properties similar to this limitation. Lerner teaches an immediate release dosage form that has a core and a mantle wherein the core contains sumatriptan and the mantle does not. It is taught that the formulation can be formulated for immediate release in the stomach. The reference teaches that the tablet (see discussion above) is capable of release 80% of the drug within 30 minutes in an aqueous system. However, one would have a reasonable expectation that subjecting to the dosage to the contents of the stomach would have similar properties if not an enhanced rate of dissolution. Moreover, the rate of disintegration of the core and mantle are similarly capable of optimization. It is well known in the art that if one desired to adjust the release profile for a capsule, adjusting the amount of disintegrant in the formulation would result in altering the rate of disintegration (i.e. adding more would increase the rate of dissolution while decreasing the amount would decrease the rate of dissolution), on the other hand if one desired to extend the drugs release from the dosage form, one would employ slow dissolving polymers or waxes. It is not inventive to determine and optimize the properties of a product taught by the prior art because optimization is routinely done in the field of formulations. And so if such an undertaking leads to the success of the invention, it is likely not a product of innovation but rather one of ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

26. **Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US 5425950) in view of Lieberman et al. (Pharma. Dosage Forms Vol. 1: tablets, 2nd edition, 1990, pp. 188-189).**

27. Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. specifically the invention comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active H_2-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for a immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). Below are the amounts that each is contained in the tablet formulation of Example 10 (see instant claims 7-9):

Core

A) Drug: Sumatriptan, 50% w/w;

B) Filler: Microcrystalline cellulose, 23% w/w;

C) Binder: Polyvinylpyrrolidone, 2% w/w;

D) Disintegrant: Microcrystalline cellulose, 23% w/w;

E) Lubricant: sodium stearyl fumerate, 2% w/w;

F) Adsorbent: not specifically disclosed, no specified w/w %; and

G) Colorant: optional (see column 5, lines 65-68; see instant claim 6)

Coating

A') Filler: Dibasic calcium phosphate, 23% w/w

B') Binder: Hydroxypropyl methylcellulose, 35% w/w

C') Disintegrant: Microcrystalline cellulose, 40% w/w

D') Lubricant: Sodium stearyl fumerate, 1% w/w

E') Adsorbent: not specifically disclosed, no specified w/w %; and

F) Colorant: optional (see column 5, lines 65-68; see instant claim 6).

28. Dandiker fails to specifically teach the inclusion of an adsorbent.

29. Lieberman et al. ('Lieberman) is text book that teaches commonly used excipients in dosage formulations. Adsorbents are useful because they are capable of retaining large quantities of water without becoming wet and it is taught (and widely known) that adsorbents are commonly used in tablets in order to prevent sticking, picking and filming during the tableting process (see page 188; see instant claim 6). It is taught that adding an adsorbent is useful for adsorbing excess moisture which causes problems as those described.

30. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teaching of Dandiker with Lieberman with a reasonable expectation for success in arriving at a pharmaceutical dosage form comprising a core containing sumatriptan and a coating free of sumatriptan wherein the core and the mantle further comprises adsorbents and/or colorants. The significance of Dandiker is that it teaches the major features of the invention, a core containing sumatriptan and a coating of the core which is free of

sumatriptan. Dandiker also discloses that the core contains a filler, a binder, a disintegrant, and a lubricant while the mantle comprises a filler a binder a disintegrant and a lubricant either close to or within the specified weight limitations. The teaching of Dandiker fails to include an adsorbent in the tablet formulation. However, at the time the invention was made, one having an ordinarily level of skill in the art would be motivated to include an adsorbent in the formulation for the reasons evidenced by Lieberman. Lieberman states that adsorbents are commonly used to prevent sticking, picking and filming during tablet processing. In order to provide a consistent tablet including an adsorbent would be preferable. Further, if a tablet contained a drug sensitive to water (i.e. hydrolysis) the stability of the drug as well as the shelf-life of the composition could be seriously affected. Thus, one would be clearly motivated to include an adsorbent into the formulation for the two reasons disclosed above. Adding a colorant to a tablet would also useful because it allows one to recognize perhaps the type or quantity of medicament contained within the tablet. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
September 17, 2008

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611